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K02 2597

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3. SUMMARY OF SAFETY AND EFFECTIVENESS

A. SPONSOR IDENTIFICATION

NewDeal SA
Parc d'Activitiés Garigliano
Rue de la Convention
38 200 VIENNE
FRANCE
Tél.: (33) 4 74 78 15 15
Fax: (33) 4 74 78 15 16

B. ESTABLISHMENT REGISTRATION NUMBER: 9615741

C. OFFICIAL CONTACT PERSON

Norman F. Estrin, Ph.D., RAC
President
Estrin Consulting Group, Inc.
9109 Copenhaver Drive
Potomac , MD 20854
Tel.: (301) 279 -2899
Fax: (301) 294-0126

D. DATE OF PREPARATION OF THIS SUMMARY: August 3, 2002

E. PROPRIETARY (TRADE) NAME: **K-FIX®**

F. COMMON NAME: K-Wire End Protector

G. CLASSIFICATION NAME AND REFERENCE

Smooth or threaded metallic bone fixation fastener

H. PROPOSED REGULATORY CLASS : Class II

I. DEVICE PRODUCT CODE: ~~LYT~~ HTY

J. REFERENCE: 21 CFR par. 888.3040

K. PANEL CODE: 87 OR Orthopedic

01.0009

K022597

L. DESCRIPTION OF DEVICE:

The **K-Fix®** pin protector is a simple and reliable system to protect patients or hospital staff from K-wire sharp ends and reduce bandages size. It presents an ergonomic profile. Thanks to its patented "Push, Lock and Twist" system, its fixation requires no instrument. An optional possibility for using **K-Fix®** on wires bent at right angle allows manual rotational and axial maneuvers for the removal of the pin. Delivered sterile, it can be used intraoperatively to protect temporarily the surgeon from cuts and pricks when placing multiple wires in a small area.

M. INDICATIONS FOR USE:

The wire protecting caps **K-FIX®** are indicated for use in the protection of protruding ends of wires.
Examples of protruding wires include:
- Osteotomies, arthrodesis or fractures management in the foot or hand.
- Fixation of small bone fragments, in long bones or small bones fractures

N. PREDICATE DEVICE: The **K-FIX®** is substantially equivalent to K-CAP-ES external protective caps from Westcon orthopedics (K914812), the Jurgan pin Ball® (K831072) from Jurgan Development and Mfg.

O. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS: **K FIX® (Newdeal)**, K-CAP-ES external protective caps (Westcon Orthopedics) and the Jurgan pin Ball® (Jurgan Development and Mfg.) are indicated for use in the protection of protuding ends of surgical wires.

Both of the **K FIX®(Newdeal)** and K-CAP-ES external protective caps (Westcon) are delivered sterile in a dispenser box of several units whereas the Jurgan pin Ball® (Jurgan Development and Mfg.) is included in a sterilizable polymer case (filled in any combination of models).

K FIX® (Newdeal), K-CAP-ES external protective caps ((Westcon Orthopedics) and the Jurgan pin Ball®(Jurgan Development and Mfg.) are made of polymer.
They are all external devices.

K FIX® (Newdeal), K-CAP-ES external protective caps (Westcon Orthopedics) and the Jurgan pin Ball® (Jurgan Development and Mfg) fit comparable ranges of wires diameters.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 1 2002

Norman F. Estrin, Ph.D.
Consultant to NewDeal SA
Estrin Consulting Group, Inc.
9109 Copenhaver Drive
Potomac, Maryland 20854

Re: K022597
Trade/Device Name: K-Fix®
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HTY
Dated: July 28, 2002
Received: August 5, 2002

Dear Dr. Estrin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html .

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K02 2597

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for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022597

(PLEASE DO NOT WRITE BELOW THIS LINE –CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use OR Over –the-counter Use

(Per 21 CFR 801.109) (Optional format 1-2-96)